EPA PESTICIDE PETITION NUMBER IN-10553

methylthio-*s*-triazine, in or on the following raw agricultural commodities.

* * * * *

[FR Doc. 2013–22107 Filed 9–10–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0284; FRL–9397–6]

Polyurethane-Type Polymers; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of polymers produced by the reaction of either 1,6-hexanediisocyanate; 2,4,4-trimethyl-1,6-hexanediisocyanate; 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate); 4,4′-methylene-bis-1,1′-cyclohexanediisocyanate; 4,4′-methylene-bis-1,1′ benzyldiisocyanate; or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethyleneglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol (also known as polyurethane-type polymers), when used as an inert ingredient in a pesticide chemical formulation. Syngenta Crop Protection, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polyurethane-type polymers on food or feed commodities.

DATES: This regulation is effective September 11, 2013. Objections and requests for hearings must be received on or before November 12, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0284, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0284 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 12, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0284, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of July 19, 2013 (78 FR 43117) (FRL–9392–9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (IN–10553) filed by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of polyurethane-type polymers produced by the reaction of either 1,6-hexanediisocyanate; 2,4,4-trimethyl-1,6-hexanediisocyanate; 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate); 4,4′-methylene-bis-1,1′-cyclohexanediisocyanate; 4,4′-methylene-bis-1,1′ benzyldiisocyanate; or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol,

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of polyurethane-type polymers, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of polyurethane-type polymers.

VIII. Other Considerations

A. Existing Exemptions From a Tolerance

There are no existing exemptions from a tolerance for polyurethane-type polymers.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for polyurethane-type polymers.

IX. Conclusion

Accordingly, EPA finds that exempting residues of polyurethane-type polymers from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these rules from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes, or otherwise have any unique impacts on local governments. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

Although this action does not require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population. One comment was received for a notice of filing from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

SPRING TRADING COMPANY

PV Shah, Ph.D.
Office of Pesticide Programs
Inert Assessment Branch
Document Processing Desk (Mail Code 7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460

March 8, 2013

Dear Dr. Shah:

Re: NOF and Pesticide Petition for the exemption for the requirement of a tolerance for a polymer inert ingredient.

Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300, is submitting a Pesticide Petition for a class of polymer compounds; Polyurethanes, CAS. No.'s 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2 as a carrier in or on the raw agricultural commodity's by adding these compounds to 40 FR, §180.960.

We have added information requested in our conference call regarding this application and we look forward to the issuance of this tolerance.

We have included a receipt for the PRIA fees associated with action I008 and we hereby request an expedited review for this petition. Please find the PRIA receipt, NOF and petition enclosed.

Thank yu for your prompt attention to this polymer petition.

Sincerely,

James Yowell

James Yowell
President
Spring Trading Company
Consultant for: Syngenta Crop Protection, LLC.

..805 West Timberwagon Circle
Spring, TX 77380-4030

Office Phone: 877-227-2597
Consultant Phone: 832-722-5113
Email: Spring_Trading@yahoo.com

U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES (OPPTS)
1200 Pennsylvania Avenue, N.W. , Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action NOF for IN-10553, polyurethane-type polymers.

RIN #: 2070-	**Docket ID #: EPA-HQ-OPP-2013-0284**	**FRL#:**

Docket Title: Inert petition IN-10553 proposing to amend 40 CFR part 180.960 to establish an exemption from the requirement of a tolerance for polyurethane-type polymers (CAS RN 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2)

Contact Information:	**Name: William Cutchin**	**Phone (703) 305-7990**
Legacy Information:		

Program Lead's Verification: I have reviewed the docket and verified the following:

All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.

Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.

The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.

Comments: No supporting documents.

Date: 4/24/13	Initials: William Cutchin	Phone: (703) 305-7990

Docket Manager's Verification and Sign-off: I hereby confirm the following:

X **The Docket ID # identified above matches our records**.

The documents identified in the attached Docket Index have been received by the Docket.

The documents have been properly processed for inclusion in EPA Dockets, as appropriate.

X **The documents either already are in the docket or are being process for inclusion in the docket.**

Comments:

Date: 4/25/2013	Signature: *Anthia Peters*	Phone: 566-0294

Program Lead's Certification: I hereby certify that:

I have completed the verification above.

I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.

I have obtained the DM's sign-off.

The docket is complete and ready for public release.

Comments:

Date:	Signature:	Phone:

Attachment: .

List of Documents Included in this Docket

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0284; FRL-9397-6]

Polyurethane-type polymers; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of polymers produced by the reaction of either 1,6-hexanediisocyanate; 2,4,4-trimethyl-1,6-hexanediisocyanate; 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate); 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate; 4,4'-methylene-bis-1,1' benzyldiisocyanate; or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethyleneglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, and octadec-9-enol (also known as polyurethane-type polymers), when used as an inert ingredient in a pesticide chemical formulation. Syngenta Crop Protection, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum.

CONCURRENCES								
SYMBOL	7101M	7101M	7505P	7505P				
SURNAME	H. Green	Wingate						
DATE	08/20/13	8/24/13	8/26/13					

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

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DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0284, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi ~~William Cutchin~~, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-~~7990~~ 7090; email address: RDFRNotices ~~*cutchin.william*~~*@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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II. Background and Statutory Findings

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dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..." and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the

7. The polymer's number average MW of 21,000 to 26,000 is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, polyurethane-type polymers meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to polyurethane-type polymers.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that polyurethane-type polymers could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of polyurethane-type polymers is 21,000 to 26,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since polyurethane-type polymers conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

There are no existing exemptions from a tolerance for polyurethane-type polymers.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for polyurethane-type polymers.

IX. Conclusion

Accordingly, EPA finds that exempting residues of polyurethane-type polymers from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes, or otherwise have any unique impacts on local governments. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

Although this action does not require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population. One comment was received for a notice of filing from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 29, 2013

Lois Rossi

Director, Registration Division, Office of Pesticide Programs.

spectroscopy (HPLC/ESI–MS/MS) detection is used to measure and evaluate the chemical rimsulfuron. Contact: Mindy Ondish, (RD), (703) 605–0723, email address: *ondish.mindy@epa.gov.*

4. *PP 2F8132.* (EPA–HQ–OPP–2013–0034). E.I. du Pont de Nemours and Co., 1007 Market St., Wilmington, DE 19898, requests to establish tolerances in 40 CFR part 180 for residues of the herbicide nicosulfuron, in or on sorghum, forage at 0.4 ppm; sorghum, grain at 0.8 ppm; and sorghum, stover at 0.05 ppm. The analytical method DuPont-32277 using reversed-phase HPLC/ESI–MS/MS detection is used to measure and evaluate the chemical nicosulfuron and its metabolite, IN–V9367. Contact: Mindy Ondish, (RD), (703) 605–0723, email address: *ondish.mindy@epa.gov.*

5. *PP 3F8179.* (EPA–HQ–OPP–2013–0476). Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide methoxyfenozide, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only the active ingredient: Methoxyfenozide, (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl) -2-(1,1-dimethylethyl) hydrazide), in or on pineapple at 0.7 ppm. The proposed tolerance is supported by magnitude of residue studies in pineapple. Liquid chromatography-mass spectroscopy (LC–MS/MS) detection methodology is available for tolerance enforcement. Contact: Olga Odiott, (RD), (703) 308–9369, email address: *odiott.olga@epa.gov.*

Amended Tolerance

1. *PP 2E8083.* (EPA–HQ–OPP–2012–0791). Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540, requests to amend the tolerance in 40 CFR 180.184(c) by deleting the regional tolerance for residues of the herbicide linuron, (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on parsley, leaves at 0.25 ppm. Contact: Laura Nollen, (RD), (703) 305–7390, email address: *nollen.laura@epa.gov.*

2. *PP 3F8152.* (EPA–HQ–OPP–2013–0411). Bayer CropScience, 2 TW Alexander Dr., Research Triangle Park, NC 27709, requests to amend the tolerance in 40 CFR 180.608 for residues of the insecticide spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl ester 2,2-dimethylbutanoate, in or on citrus, oil from 20 ppm to 35 ppm. Adequate analytical methodology using LC/MS/MS detection is available for enforcement purposes. Contact: Rita Kumar, (RD), (703) 308–8291, email address: *kumar.rita@epa.gov.*

3. *PP 3F8161.* (EPA–HQ–OPP–2013–0477). BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to amend the tolerance in 40 CFR 180.666 for residues of the insecticide fluxapyroxad (BAS 700 F), 1*H*-pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-, its metabolites, and degradates, in or on fruit, stone, group 12 from 2.0 ppm to 3.0 ppm. Independently validated analytical methods have been submitted for analyzing residues of parent fluxapyroxad (BAS 700 F) plus metabolites M700F008, M700F048, and M700F002 with appropriate sensitivity in/on fruit, stone, group 12 crops, represented by cherry, peach, and plum for which tolerances have been established. Contact: Olga Odiott, (RD), (703) 308–9369, email address: *odiott.olga@epa.gov.*

New Tolerance Exemption

1. *PP 2E8094.* (EPA–HQ–OPP–2013–0265). The Clorox Company (Clorox), 1221 Broadway, Oakland, CA 94612–1888, requests to establish an exemption from the requirement of tolerance for residues of saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids, under 40 CFR 180.940, when used as pesticide inert ingredients (fragrances) in pesticide formulations used on food-contact surfaces when applied/used in indoor residential settings at a maximum rate of 0.025%. Because Clorox is petitioning for an exemption from the requirement of a tolerance, an enforcement analytical method is not needed. Contact: David Lieu, (RD), (703) 305–0079, email address: *lieu.david@epa.gov.*

2. *PP 2E8116.* (EPA–HQ–OPP–2013–0286). OhSo Clean, Inc., 315 Pacific Ave., San Francisco, CA 94111, requests to establish an exemption from the requirement of a tolerance for residues of copper sulfate pentahydrate (Chemical Abstracts Service Registry Number (CAS No.) 7758–99–8), under 40 CFR 180.940(a), when used as a pesticide inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Contact: David Lieu, (RD), (703) 305–0079, email address: *lieu.david@epa.gov.*

3. *PP 2F7998.* (EPA–HQ–OPP–2013–0102). Linde Electronics and Specialty Gases, One Greenwich St., Suite 100, Stewartsville, NJ 08886, requests to establish an exemption from the requirement of a tolerance for residues of the insecticide ethyl formate in or on fumigated agricultural commodities. The GC analytical method is available to EPA for the detection and measurement of the pesticide residues. Contact: Cheryl Greene, (BPPD), (703) 308–0352, email address: *greene.cheryl@epa.gov.*

4. *PP 3F8149.* (EPA–HQ–OPP–2013–0253). Bayer CropScience LP, Biologics, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709, requests to establish an exemption from the requirement of a tolerance for residues of the insecticide *Streptomyces microflavus,* strain AQ 6121, in or on all agricultural commodities. The petitioner believes no analytical method is needed because it is expected that, when used as proposed, *Streptomyces microflavus,* strain AQ 6121, would not result in residues of toxicological concern. Contact: Michael Glikes, (BPPD), (703) 305–6231, email address: *glikes.michael@epa.gov.*

5. *PP IN–10547.* (EPA–HQ–OPP–2013–0444). Oro-Agri, Inc., 990 Trophy Club Dr., Trophy Club, TX 76262, requests to establish an exemption from the requirement of a tolerance for residues of sweet orange peel tincture (CAS No. 8028–48–6) under 40 CFR 180.910 for pre- and post-harvest crops when used as a pesticide inert ingredient (surfactant and fragrance) when contained at concentrations up to 10% in pesticide formulations and applied to agricultural crops, pre-plant through post-harvest. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. Contact: Lisa Austin, (RD), (703) 305–7894, email address: *austin.lisa@epa.gov.*

6. *PP IN–10553.* (EPA–HQ–OPP–2013–0284). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300, requests to establish an exemption from the requirement of a tolerance for residues of polyurethane-type polymers (CAS Nos. 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2), under 40 CFR 180.960, when used as a pesticide inert ingredient (carrier) in or on raw agricultural commodities and

Cutchin, William D.

From: James Yowell [james@springtradingcompany.com]
Sent: Wednesday, April 17, 2013 3:38 PM
To: Cutchin, William D.; Spring_Trading@yahoo.com
Cc: Shah, Pv; Leifer, Kerry; alex.heming@syngenta.com
Subject: RE: Polyurethane-type Polymer Inert Petition
Attachments: Syngenta submission new info 2-2013 polyurethanes.docx

William:

The attached information should have been included in the submission and should clear up the mw and methods questions. Please let me know if additional information is needed.

James Yowell,
President
Spring Trading Company

Office Phone: 877-227-2597 (US)
Consultant Phone: 832-722-5113

James@springtradingcompany.com

From: Cutchin, William D. [mailto:Cutchin.William@epa.gov]
Sent: Wednesday, April 17, 2013 1:17 PM
To: Spring_Trading@yahoo.com
Cc: Shah, Pv; Leifer, Kerry
Subject: Polyurethane-type Polymer Inert Petition

Mr. Yowell,

In reviewing your petition, IN-10553, for the use of polyurethane-type polymers as an inert in pesticide formulations, we have some questions concerning the validity of the determination of the number average molecular weight (nMW) of the polymers.

The accepted analytical method to determine nMW, gel permeation chromatography, was not used. The reasoning given that "..no mobile/soluble polymer molecules are detectable" has no supporting data. In addition, "An analytical method to determine the MW of the polymer is dynamic light scattering" is mentioned in the submitted NOF without further explanation. Instead a numerical calculation method was used in the submission, which is not adequately explained. The results of 17,000 Daltons and nMWs of 1000 and 500 at less than 0.1% concentration in the inert are not supported.

Please, provide the proper analytical data or a more complete explanation of the proposed calculation method.

Thank you,
Bill C.

William Cutchin, Chemist
Inert Ingredient Assessment Branch (7505P)
(703) 305-7990
PY-7828S

Syngenta submission to EPA for tolerance exemption of certain polyurethanes

Petition for Approval of an Inert Ingredient Low Risk Polymer Exemption under 40 CFR 180.960

Hydrophobically modified urethane rheology modifiers (HEURs) with number average molecular weights of 21,000 to 26,000 Daltons. This includes the following polymers registered with CAS.

1161844-26-3

1161844-30-9

1161844-43-4

1161844-51-4

693252-31-2

630102-86-2

162993-60-4

Summary

Polyurethanes with a number average molecular weight greater than 17,000 Daltons produced by the reaction of one of 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 1,6-hexanediisocyanate with polyethylenglycol and end-capped with one or a mixture of more than one of 1-octanol, 1-nonanol, 1-decanol, 1-undecanol, 1-hexadecanol, 1-octadecanol and 1-octadec-9-enol or polyethyleneglycol ethers of 1-octanol, 1-nonanol, 1-decanol, 1-undecanol, 1-hexadecanol, 1-octadecanol and 1-octadec-9-enol.

For the purpose of rheology modification in liquid formulations of pesticides.

The compounds meet the requirements of Low Risk Polymer on all criteria 1-6 and 7, option 2, in that they are organic polymers consisting entirely of C, H, N and O, are not cationic, do not readily degrade, are prepared from monomers on the TSCA registry, are not strongly water absorbing and have a number average molecular weight of greater than 10,000 Daltons and less than 5% by weight of the polymer is below 1000 Daltons and less than 2% by weight of the polymer is below 500 Daltons.

List of Data Included

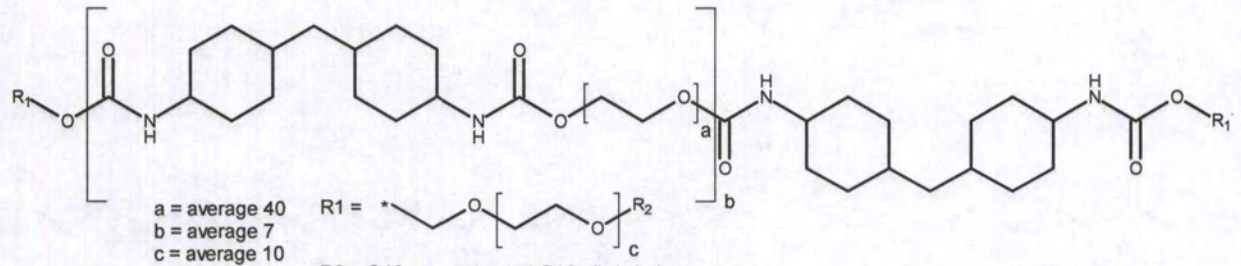
Page 2. Molecular weight summary and Gel Permeation Chromatograms

Page 3. Representative Structures

Page 5. List of monomers used in the preparation

Representative Structures of the polyurethane polymers

CAS 1161844-26-3

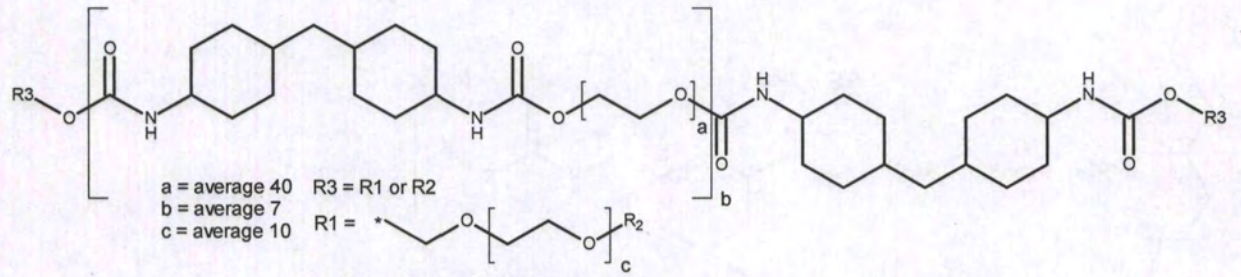


a = average 40
b = average 7
c = average 10

R1 =

R2 = C16 or unsaturated C18 alkyl chain

CAS 1161844-30-9



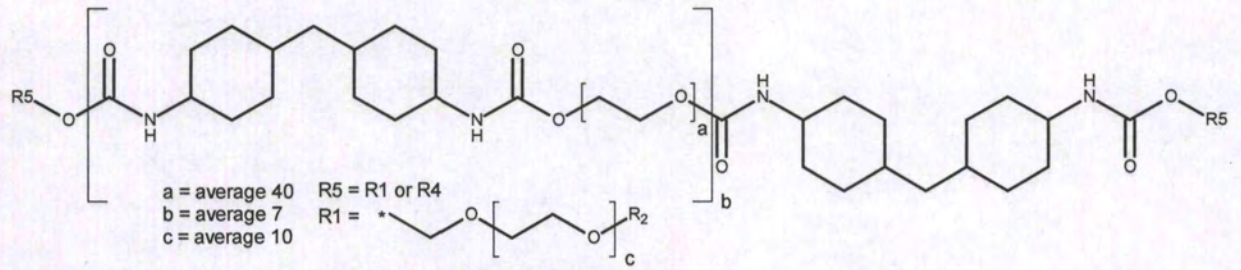
a = average 40
b = average 7
c = average 10

R3 = R1 or R2

R1 =

R2 = C16 or unsaturated C18 alkyl chain

CAS 1161844-43-4



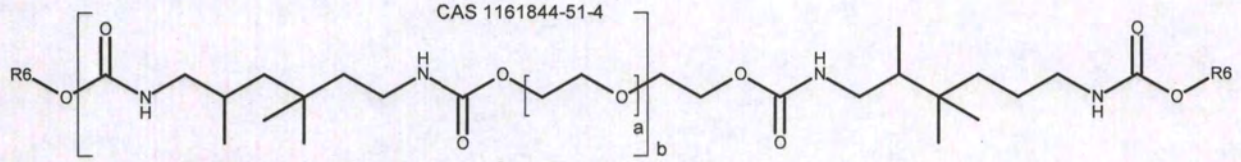
a = average 40
b = average 7
c = average 10

R5 = R1 or R4

R1 =

R2 = C16 or unsaturated C18 alkyl chain
R4 = C9-11 iso-alkyl chain

CAS 1161844-51-4



a = average 40
b = average 7

R6 = R2 or R4
R4 = C9-11 iso-alkyl chain
R2 = C16 or unsaturated C18 alkyl chain

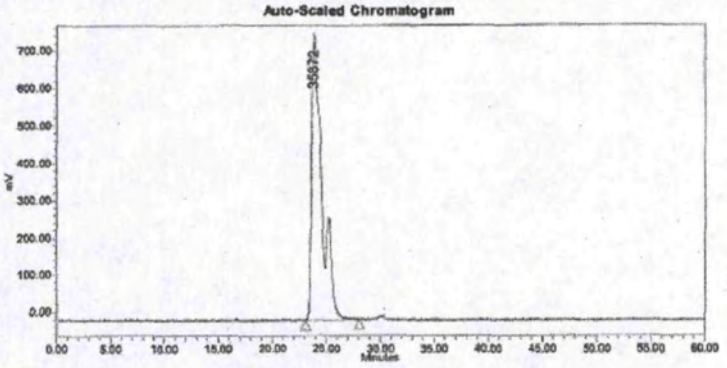
List of monomers used in the preparation

Compound	CAS number
4,4'-methylene-bis-1,1'-cyclohexanediisocyanate	5124-30-1
2,4,4-trimethyl-1,6-hexanediisocyanate	15646-96-5
5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate)	4098-71-9
1,6-hexanediisocyanate	88357-62-4
polyethylenglycol	25322-68-3
1-octanol	111-87-5
1-nonanol	143-08-8
1-decanol	112-30-1
1-undecanol	112-42-5
1-hexadecanol	36653-82-4
1-octadecanol	112-92-5
1-octadec-9-enol	143-28-2

Borchi® Gel 0620, 0939-03-0562

Sample Name:	Borchi Gel 0620 - SV	Acquired By:	damrcjv
Sample Type:	Broad Unknown	Date Acquired:	11/18/2008 10:42:20 AM CET
Vial:	19	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/19/2008 4:31:22 PM CET
Injection Volume:	5.00 ul	Processing Method	13877_PM_2
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name	13877_3	Proc. Chnl. Descr.	ELSD
HPLC_column PSgel		System Name AL3_PDA3_ELSD1	
Labjournal dosier		System Node Ntw-egg	
^awdata dosier		TNOid sample 3A	

Auto-Scaled Chromatogram



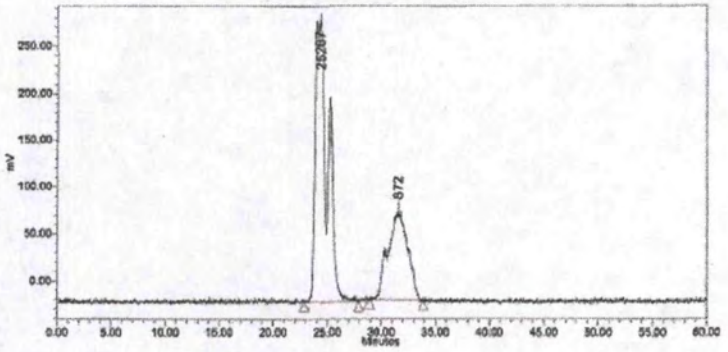
GPC Results

	Dist Name	Mn	Mw	Mv	MP	Mz	Mz+1	Polydispersity	K	alpha
1		24071	27714		35872	30664	32942	1.151320		

Borchi® Gel 0621, 0939-03-0571

Sample Name:	Borchi Gel 0621 - 10V	Acquired By:	damrcjv
Sample Type:	Broad Unknown	Date Acquired:	11/18/2008 12:44:16 PM CET
Vial:	21	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/19/2008 4:30:49 PM CET
Injection Volume:	5.00 ul	Processing Method	13877_PM_2
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name	13877_3	Proc. Chnl. Descr.	ELSD
HPLC_column PSgel		System Name AL3_PDA3_ELSD1	
Labjournal dosier		System Node Ntw-eqg	
wdata dosier		TNOid sample 4A	

Auto-Scaled Chromatogram



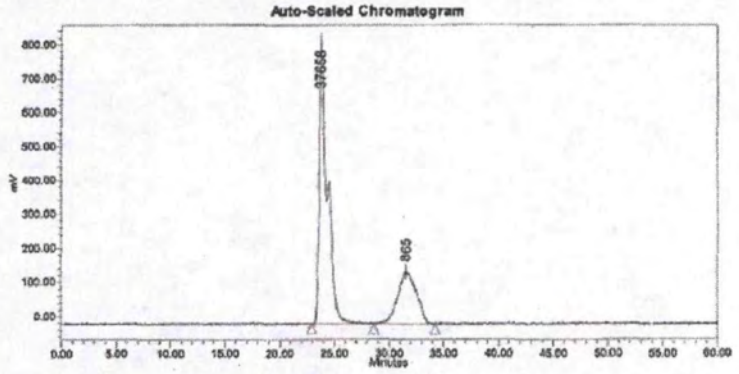
GPC Results

	Dist Name	Mn	Mw	Mv	MP	Mz	Mz+1	Polydispersity	K	alpha
1		20677	23643		25267	26509	28807	1.158736		
2					872					

Borchi® Gel 0625, 0939-03-0564

Sample Name:	Borchi Gel 0625 - 10V	Acquired By:	damrcjv
Sample Type:	Broad Unknown	Date Acquired:	11/18/2008 4:48:40 PM CET
Vial:	25	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/19/2008 4:29:40 PM CET
Injection Volume:	5.00 ul	Processing Method	13877_PM_2
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name	13877_3	Proc. Chnl. Descr.	ELSD
HPLC_column PSgel		System Name AL3_PDA3_ELSD1	
Labjournal dosler		System Node Ntw-eqg	
nwdata dosler		TNOid sample 6A	

Auto-Scaled Chromatogram



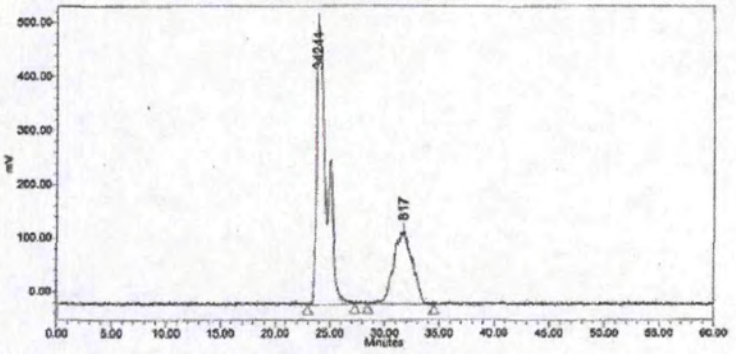
GPC Results

	Dist Name	Mn	Mw	Mz	MP	Mz	Mz+1	Polydispersity	K	alpha
1		26373	30129		37658	33658	34587	1.142405		
2					865					

Borchi® Gel 0626, 0939-03-0565

Sample Name:	Borchi Gel 0626 - 10V	Acquired By:	damrcjv
Sample Type:	Broad Unknown	Date Acquired:	11/18/2006 8:53:11 PM CET
Vial:	27	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/19/2006 4:28:12 PM CET
Injection Volume:	5.00 ul	Processing Method	13877_PM_2
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name	13877_3	Proc. Chnl. Descr.	ELSD
HPLC_column PSgel		System Name AL3_PDA3_ELSD1	
Labjournal dosier		System Node Ntw-eag	
Rawdata dosier		TNOid sample 7A	

Auto-Scaled Chromatogram



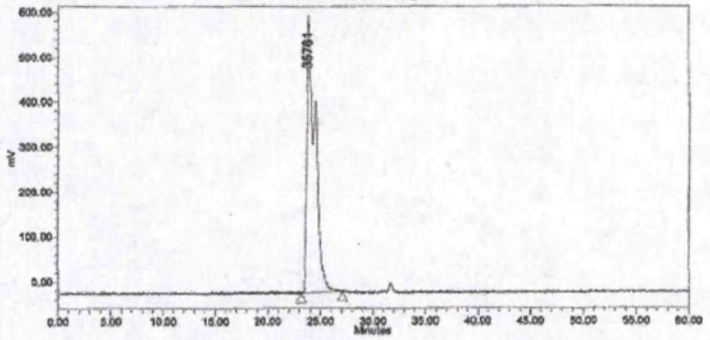
GPC Results

	Dist Name	Mn	Mw	Mv	MP	Mz	Mz+1	Polydispersity	K	alpha
1		23539	26758		34241	29430	31578	1.136755		
2					817					

Borchi® Gel 0434/0939-03-0560

Sample Name:	Borchi Gel 0434 - 10V	Acquired By:	damrcjv
Sample Type:	Broad Unknown	Date Acquired:	11/18/2008 8:40:27 AM CET
Vial:	17	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/19/2008 4:32:00 PM CET
Injection Volume:	5.00 ul	Processing Method	13877_PM_2
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name	13877_3	Proc. Chnl. Descr.	ELSD
HPLC_column PSgel		System Name AL3_PDA3_ELSD1	
Labjournal dosier		System Node Ntw-eqg	
iwdata dosier		TNOid sample 1A	

Auto-Scaled Chromatogram



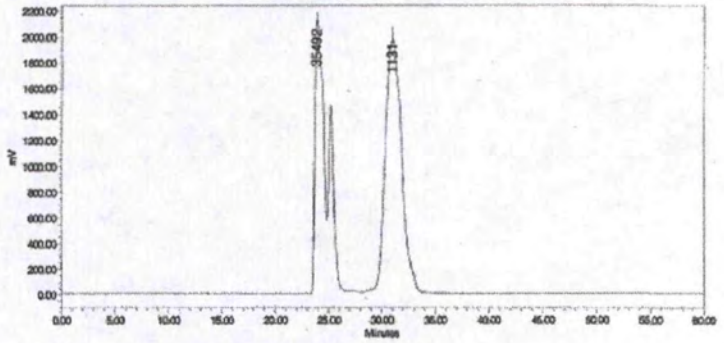
GPC Results

	Dist Name	Mn	Mw	Mv	MP	Mz	Mz+1	Polydispersity	K	alpha
1		25721	28038		35761	30970	31514	1.090122		

Borchi® Gel 0435, 0939-03-0561

Sample Name:	Borchi Gel 0435	Acquired By:	damrcjv
Sample Type:	Broad Unknow n	Date Acquired:	11/15/2008 2:18:56 PM CET
Vial:	20	Acq. Method Set:	13877_MS
Injection #:	1	Date Processed:	11/18/2008 5:05:38 PM CET
Injection Volume:	5.00 ul	Processing Method:	13877_PM
Run Time:	60.0 Minutes	Channel Name:	SATIN
Sample Set Name:	13877_1	Proc. Chnl. Descr.:	ELSD
HPLC_column PSgel		System Name A13_PDA3_ELSD1	
Labjournal dosier		System Node Ntw - eqg	
Raw data dosier		TNOld sample 2A	

Auto-Scaled Chromatogram



GPC Results

	Dist Name	Mn	Mw	Mv	MP	Mz	Mz+1	Polydispersity	K	alpha
1		23131	24882		35492	26141	31055	1.177796		
2		965	1091		1139	1215	1356	1.129660		

Software Version :< 6.2 > Sample Name :Gel_L75N Operator :steith
Injection Time : Sample Number :009 Study :
Report Printed :07.12.2012 08:29:30 Interface Serial# :9116290021
Raw File :D:\TC_DATEN\ALLE\MESSUNGEN\GPC\2012\06_12_12_GEL_L75N_UND_L76\GEL_L75N_009_LICHTSTREU-DETEKTOR_
Result File :D:\TC_DATEN\ALLE\MESSUNGEN\GPC\2012\06_12_12_GEL_L75N_UND_L76\GEL_L75N_009_LICHTSTREU-DETEKTOR_
Method File :D:\TC_DATEN\ALLE\METHODEN\GPC\GPC_AUSWERTUNG_PE.SEC
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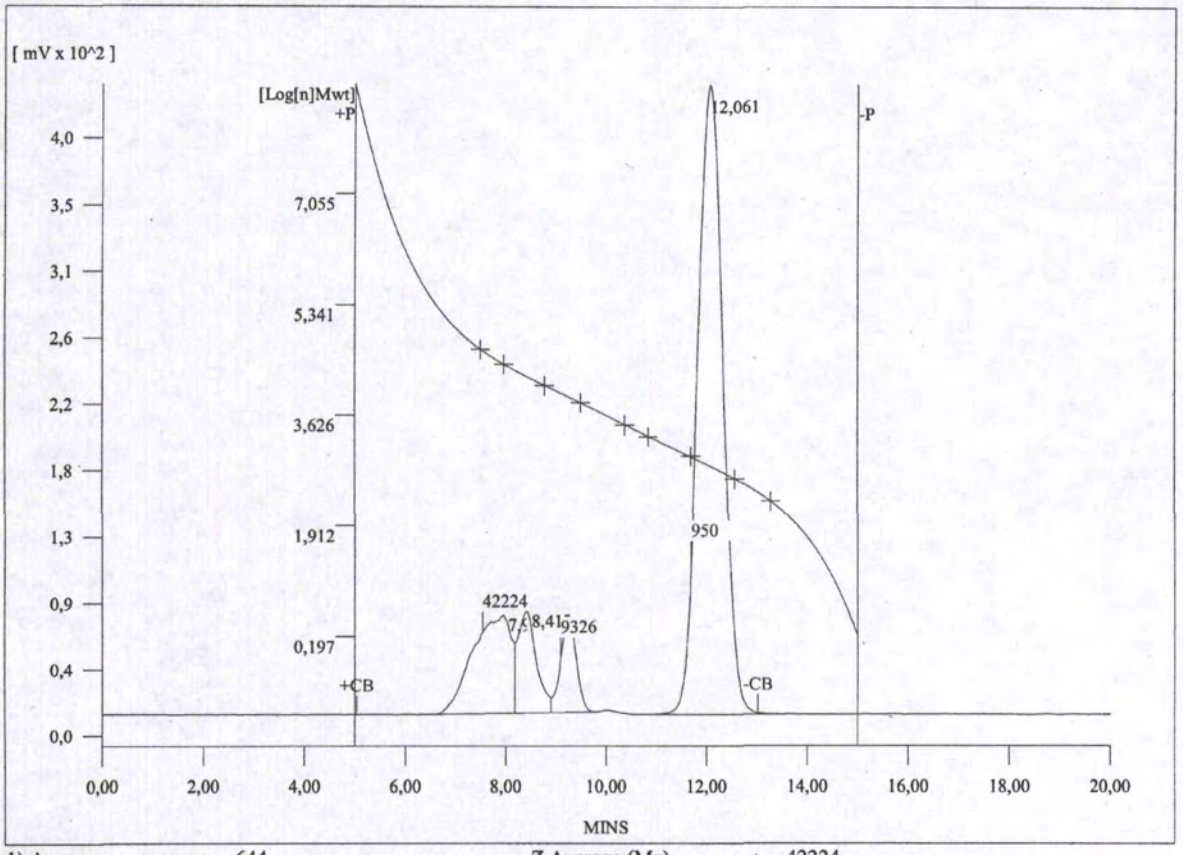
Modified :12/07/12 08:29:06 AM



(n - 1) Average : 644 Z Average (Mz) : 42224
Number Average (Mn) : 950 (Z + 1) Average : 64153
Weight Average (Mw) : 9326 PolyDispersity (Mw/Mn) : 9,819
Total Area : 2,1392206e+007 (microvolt seconds)

Peak Molecular Weight Report

Peak	Component	RT	Area	%Area	PMwt	Mw	Mn	Mw/Mn	StartMw	EndMw
1		7,945	3,55e+006	16,575	26605,4	41962,5	35252,6	1,1903	234737,3	20965,5
2		8,417	1,75e+006	8,166	16889,3	16562,5	16186,1	1,0233	20965,5	10984,4
3		9,248	1,41e+006	6,579	8178,1	8242,0	8115,0	1,0156	10984,4	5127,4
4		12,061	1,47e+007	68,680	691,6	692,8	663,5	1,0441	1899,8	154,1

21-Day Screen Completed by Contractor

21-Day Expires on 4-3-13

Jacket # IN-10553
MRID# _____

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAIBLE

NEW APPLICATIONS

DATE: MAR 13 2013

FILE REG NUMBER: IN-10553

FEP (OPPIN ENTRY) LV MAR 14 2013

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD ✓ **RD** 8 **BPPD** _____

_____ **JACKET TO SHELF (DATA)**

REVISED 11/28/12

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3/13/13

Experts In-Processing Signature: MP Date 3/15/13 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: IN-10553	EPA Receipt Date: 3/13/13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type					X
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					Y
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)					Y
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					Y
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)					Y
		yes	**no**			
	a) Selective Method (Fee category experts use)					
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)					X

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)			X
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**	X		
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Notice of Filing present inside Petition.

PRN 11-03 review - N/A

Petition - Passed

SS/03-19-13

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

SPRING TRADING COMPANY

PV Shah, Ph.D.
Office of Pesticide Programs
Inert Assessment Branch
Document Processing Desk (Mail Code 7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460

March 8, 2013

Dear Dr. Shah:

Re: NOF and Pesticide Petition for the exemption for the requirement of a tolerance for a polymer inert ingredient.

Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300, is submitting a Pesticide Petition for a class of polymer compounds; Polyurethanes, CAS. No.'s 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2 as a carrier in or on the raw agricultural commodity's by adding these compounds to 40 FR, §180.960.

We have added information requested in our conference call regarding this application and we look forward to the issuance of this tolerance.

We have included a receipt for the PRIA fees associated with action I008 and we hereby request an expedited review for this petition. Please find the PRIA receipt, NOF and petition enclosed.

Thank yu for your prompt attention to this polymer petition.

Sincerely,

James Yowell

James Yowell
President
Spring Trading Company
Consultant for: Syngenta Crop Protection, LLC.

..805 West Timberwagon Circle
Spring, TX 77380-4030

Office Phone: 877-227-2597
Consultant Phone: 832-722-5113
Email: Spring_Trading@yahoo.com

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

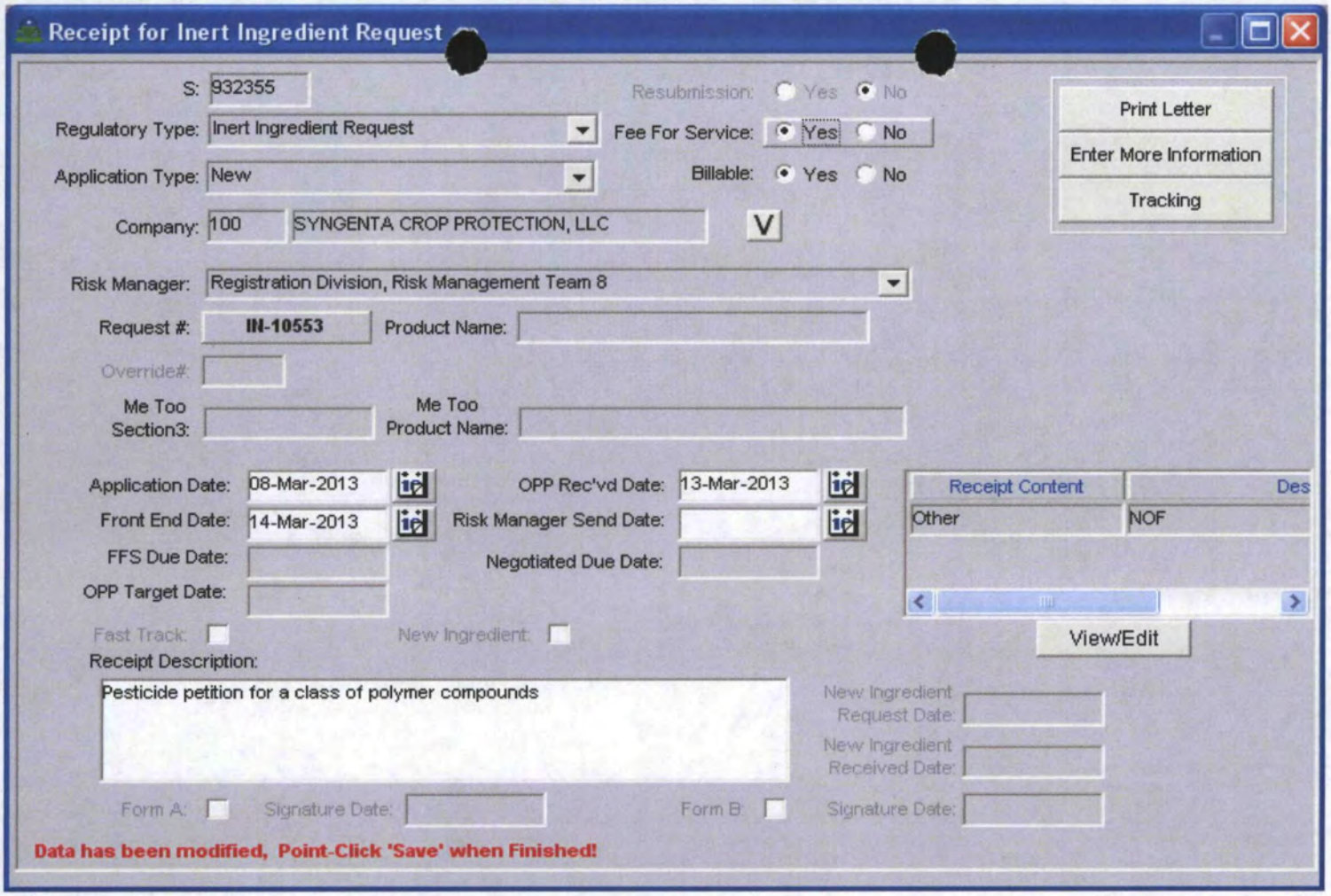
Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 259SHQ91
Agency Tracking ID: 74420119842
Transaction Date and Time: 03/07/2013 09:02 EST

Payment Summary

Address Information		Account Information		Payment Information	
Account Holder Name:	James Yowell	**Card Type:**	Master Card	**Payment Amount:**	$3,400.00
Billing Address:	10805 W. Timberwagon Cir.	**Card Number:**	**********8827	**Transaction Date and Time:**	03/07/2013 09:02 EST
Billing Address 2:		**Decision Number:**			
City:	Spring	**Registration Number:**			
State / Province:	TX	**Company Name:**	Syngenta Crop Protection,		
Zip / Postal Code:	77380-4030	**Company Number:**	100		
Country:	USA	**Action Code:**	I008		


Receipt for Inert Ingredient Request
S: 932355
Resubmission: Yes No
Regulatory Type: Inert Ingredient Request
Fee For Service: Yes No
Application Type: New
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, LLC
V
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 8
Request #: IN-10553
Product Name:
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 08-Mar-2013
OPP Rec'vd Date: 13-Mar-2013
Front End Date: 14-Mar-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Other
NOF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Pesticide petition for a class of polymer compounds
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:
Data has been modified, Point-Click 'Save' when Finished!

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 15, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-476335
EPA Petition Number: IN-10553
Product Name: Polyurethanes
EPA Receipt Date: 13-Mar-2013
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, LLC

MS. BUNNIE KONAT
SYNGENTA CROP PROTECTION, LLC
410 SWING ROAD, PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: I008

Approval of New Polymer Inert Ingredient;FOOD USE;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703)308-9362.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{932355,~

This package includes the following

- ◉ New Registration
- ○ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 8

Receipt No. S-	932355
EPA File Symbol/Reg. No.	IN-10553
Pin-Punch Date:	3/13/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: 1008

Granted: 1008

Amount Due: $ 3400.00

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: [signature] Date: 3/14/13

Remarks:

EPA REGISTRATION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

EPA Registration Division contact: [PV Shah, Branch Chief Inert Assessment Branch (IAB) 703-308-1846]

INSTRUCTIONS: **Please utilize this outline in preparing the pesticide petition. In cases where the outline element does not apply, please insert "NA-Remove" and maintain the outline. Please do not change the margins, font, or format in your pesticide petition. Simply replace the instructions that appear in green, i.e., "[insert company name]," with the information specific to your action.**

TEMPLATE:

[Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300]

[TBD Petition Number]

EPA has received a pesticide petition **([TBD insert petition number])** from **[Syngenta Crop Protection, LLC], [, P.O. Box 18300, Greensboro, NC 27419-8300]** proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.

(Options 2. (pick one)

To establish an exemption from the requirement of a tolerance for the polymer:

[Polyurethanes,CAS. No.'s 1161844-26-3, 1161844-30-9, 1161844-43-4, 1161844-51-4, 1161844-53-6, 693252-31-2, 162993-60-4, and 630102-86-2 as a carrier] in or on the raw agricultural commodity's [IN OR ON RAW AGRICULTURAL PRODUCTS AND FOOD PRODUCTS. PER FR, §180.960] [Tolerance exemption descriptors for Polymers produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of FDDCA; however, EPA has not fully evaluated the

sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Waived under the polymer exemption definition.

2. *Analytical method.* **[An analytical method to determine the MW of the polymer is dynamic light scattering]**

3. *Magnitude of residues.* **[Waived under the polymer exemption definition]**

B. Toxicological Profile

The available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children for the low risk polymer classification.

These Polyurethane polymers are not acutely toxic by the oral and dermal routes of exposure, or via inhalation under normal use conditions. Concentrated materials are generally not corrosive, eye and skin irritants and not dermal sensitizers. There is no evidence that these Polyurethane polymers are neurotoxic, mutagenic, or clastogenic.

Specific information on the studies evaluated and the nature of the adverse effects findings by Polyurethane-type polymers as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in documents allowing the approval of defined low risk polymeric compounds.

1. *Acute toxicity.* **[Waived under the polymer exemption definition.]**

2. *Genotoxicty.* **[NA.]**

3. *Reproductive and developmental toxicity.* **[NA.]**

4. *Subchronic toxicity.* [NA.]

5. *Chronic toxicity.* [Cancer. Syngenta used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential carcinogenicity of several representative large molecular weight polymers such

as the Polyurethane-type polymers and no structural alerts for carcinogenicity were identified in any case. Polyurethane-type polymers are not expected to be carcinogenic. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.NA.]

6. *Animal metabolism.* **[NA.]**

7. *Metabolite toxicology.* **[NA.]**

8. *Endocrine disruption.* **[This class of chemistry does not belong to a class of chemicals known or suspected of having adverse effects on the estrogen receptor or endocrine system.]**

C. Aggregate Exposure

1. *Dietary exposure.* [In evaluating dietary exposure to Polyurethane-type polymers, Syngenta considered exposure under the polymer exemption classification and established a definition for molecules that meet the criteria of that definition qualify for exemption from the requirement of a tolerance. EPA assessed dietary exposures from large molecular weight polymers in food as follows: First acute and chronic exposure; In conducting the acute and chronic dietary exposure assessments, Syngenta used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for the Polyurethane-type polymers. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the dietary exposure and risk assessment for low risk polymers can be found at http://www.regulations.gov.]

Syngenta believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk based on the EPA assessment and definition requirements for these polymers. Assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 15 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product relative to that of the active ingredient. In the case of Polyurethane-type polymers, EPA made a specific definition of what constitutes an acceptable polymeric compound and the proposed exemption for Polyurethane-type polymers meets that criteria.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the conservative assumptions will lead to a significant exaggeration of

actual exposures. Syngenta does not believe that this approach underestimates exposure in the absence of residue data.

i. *Food.* [NA]

ii. *Drinking water.* [Syngenta used screening level water exposure models in the dietary exposure analysis and risk assessment for Polyurethane-type polymers in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of large molecular weight polymers. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at: http://www.epa.gov/oppefed1/models/water/index.htm.NA]

2. *Non-dietary exposure.* [The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Polyurethane-type polymers may be used as inert ingredients in pesticide products that are registered for specific uses that could result in indoor residential exposures.

A screening level residential exposure and risk assessment was completed for polymeric products used as inert ingredients in pesticide formulations. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for outdoor scenarios with high exposure potential (i.e., exposure scenarios with high end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing Polyurethane-type polymers. Similarly, residential post application dermal and oral exposure assessments were also performed utilizing high end outdoor exposure scenarios. Analysis can be found at http://www.regulations.gov in documents on the polymer exemption risk assessment.]

D. Cumulative Effects [Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity.

Syngenta has not found that Polyurethane-type polymers share a common mechanism of toxicity with any other substances, and Polyurethane-type polymers do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, Syngenta has assumed that Polyurethane-type polymers do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at http://www.epa.gov/pesticides/cumulative.]

E. Safety Determination [*EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD*

and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.]

1. *U.S. population.* [**Determination of safety: based on the risk assessments conducted by the agency, Syngenta concludes that there is a reasonable certainty that no harm will result to the general population**]

2. *Infants and children.* [Syngenta **has determined that EPA has reviewed reliable data that show the safety of infants and children would be adequately protected.**]

F. International Tolerances

[Syngenta **is not aware of any country requiring a tolerance for these Polyurethane-type polymers nor have any CODEX Maximum Residue Levels been established for any food crops at this time.**]

TITLE

PETITION FOR EXEMPTION FROM TOLERANCE

PRODUCT IDENTIFICATION, PRPOSED DESCRIPTOR

Petition proposing an exemption from the requirement of a tolerance for Polyurethanes produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

AUTHOR

James Yowell

VOLUMN NUMBER
2 of 2

COMPLETION DATE

March 8, 2013

SUBMITTED BY

Syngenta Crop Protection, LLC
C/O Spring Trading Company
10805 W. Timberwagon Circle
Spring, Texas 77380-4030

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA §10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Submitter: James Yowell Date: March 8, 2013

Typed Name of Signer: James Yowell

Typed Name of Company: **Syngenta Crop Protection, LLC**
C/O Spring Trading Company
10805 W. Timberwagon Circle
Spring, Texas 77380-4030

GOOD LABORATORY PRACTICE STATEMENT

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160.

This is a request for waiver of specific data requirements. It is supported by data from studies conducted using sound scientific practices, but not under GLP procedures. Therefore 40 CFR 160 requirements are not applicable.

Submitter: James Yowell Date: March 8, 2013

Typed Name of Signer: James Yowell

Typed Name of Company: **Syngenta Crop Protection, LLC**
C/O Spring Trading Company
10805 W. Timberwagon Circle
Spring, Texas 77380-4030

Petition proposing an exemption from the requirement of a tolerance for Polyurethanes produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

Summary:

This petition is to establish an exemption from the requirement of a tolerance for residues of Polyurethanes with a number average molecular weight greater than 17,000 Daltons produced by the reaction of one of 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 1,6-hexanediisocyanate with polyethylenglycol and end-capped with one or a mixture of more than one of 1-octanol, 1-nonanol, 1-decanol, 1-undecanol, 1-hexadecanol, 1-octadecanol and 1-octadec-9-enol or polyethyleneglycol ethers of 1-octanol, 1-nonanol, 1-decanol, 1-undecanol, 1-hexadecanol, 1-octadecanol and 1-octadec-9-enol.

These Hydrophobically modified urethane rheology modifiers (HEURs) with number average molecular weights of 21,000 to 26,000 Daltons are for the purpose of rheology modification in liquid formulations of pesticides.

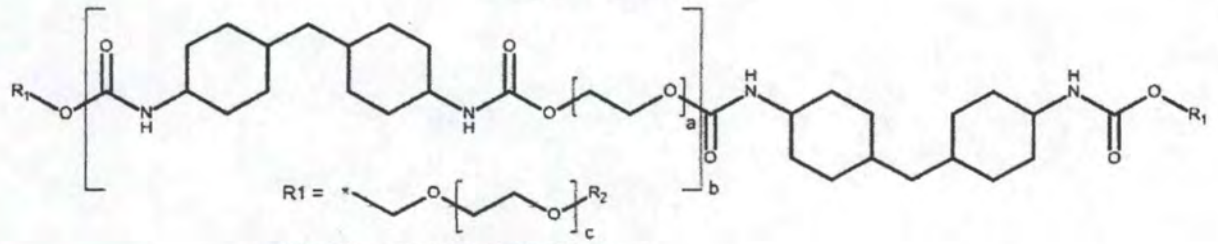
The compounds meet the requirements of Low Risk Polymer on all criteria 1-6 and 7, option 2, in that they are organic polymers consisting entirely of C, H, N and O, are not cationic, do not readily degrade, are prepared from monomers on the TSCA registry, are not strongly water absorbing and have a number average molecular weight of greater than 10,000 Daltons and less than 5% by weight of the polymer is below 1000 Daltons and less than 2% by weight of the polymer is below 500 Daltons.

polymer polyurethane combinations when used as inert ingredients in pesticide formulations applied to growing crops and animals. The descriptor and the list of proposed combinations of polyurethane combinations is not intended to be an inclusive list of all the possible combinations of acceptable polyurethane-type polymers. This petition is being submitted to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This petition for a polymer that meets the low risk polymer definition eliminates the need to establish a maximum permissible level for residues of the listed polyurethane-type polymers. Since these polyurethane-type polymers meet the requirements of the 40 CFR § 180.960 and we propose a chemical description meeting the polymer exemption requirements, we are petitioning the Agency to issue this description as an exempt polymer in the FR.

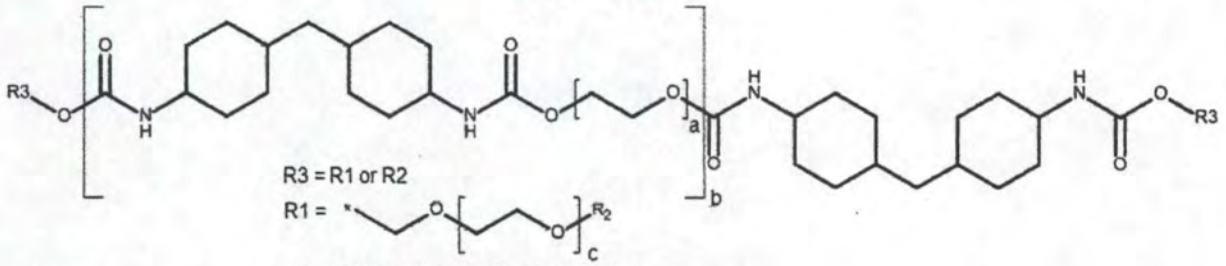
Petition proposing an exemption from the requirement of a tolerance for Polyurethanes produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

1. **Representative structure (Diagram of polymer)**

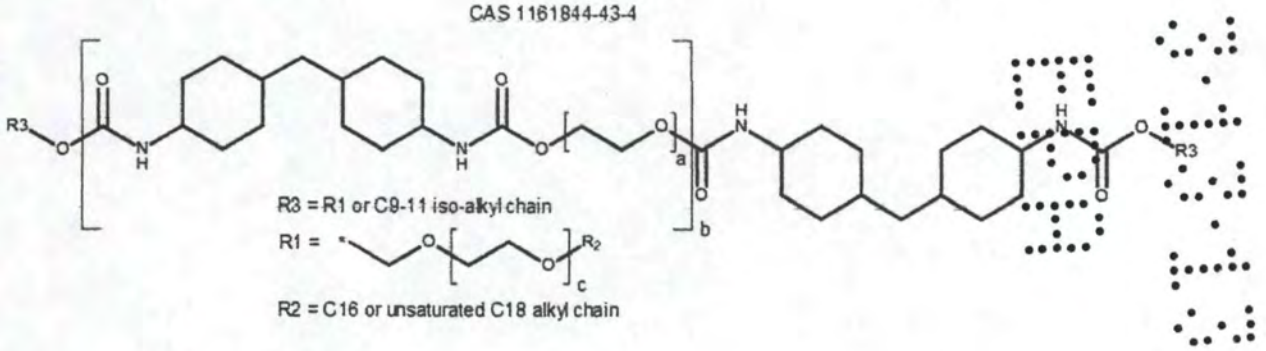
CAS 1161844-26-3



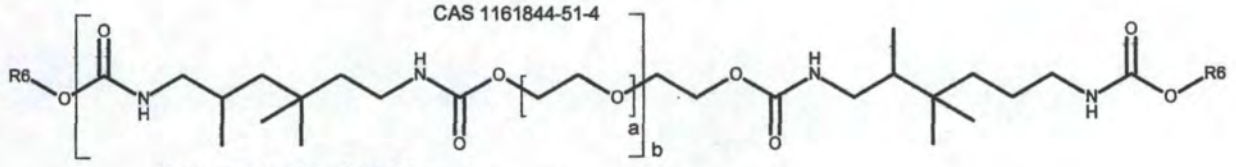
CAS 1161844-30-9



CAS 1161844-43-4

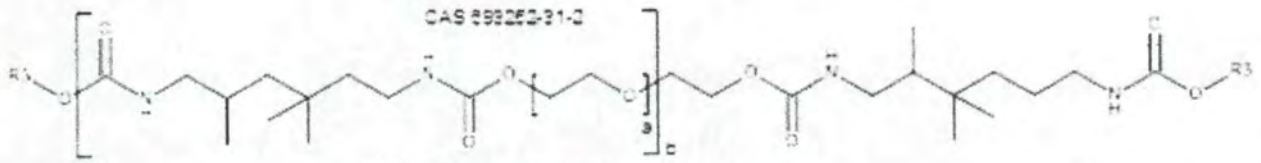


Petition proposing an exemption from the requirement of a tolerance for Polyurethanes produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

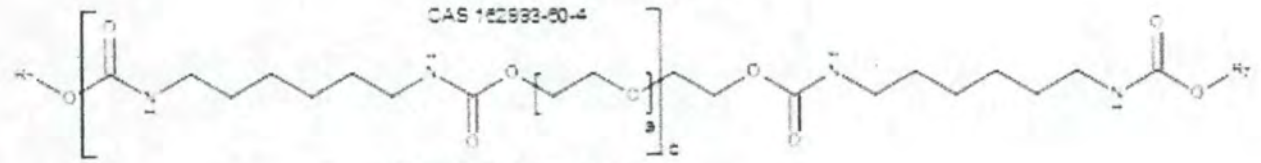


a = average 40
b = average 7

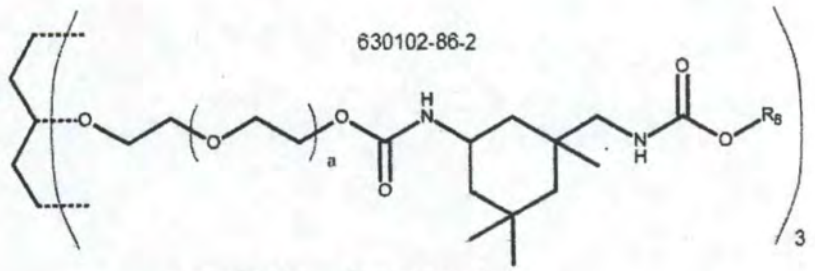
R6 = R2 or R4
R4 = C9-11 iso-alkyl chain
R2 = C16 or unsaturated C18 alkyl chain



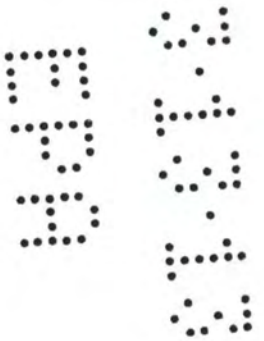
R3 = C9-11 iso-alkyl chain



R7 = C18 saturated n-alkyl chain



a = average 40 R8 = C8 or C10 alkyl



Petition proposing an exemption from the requirement of a tolerance for Polyurethanes produced by the reaction of either 1,6-hexanediisocyanate, 2,4,4-trimethyl-1,6-hexanediisocyanate, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate), 4,4'-methylene-bis-1,1'-cyclohexanediisocyanate, 4,4'-methylene-bis-1,1'-benzyldiisocyanate or 1,3-bis-(2-isocyanatopropan-2-yl)benzene with polyethylenglycol and end-capped with one or a mixture of more than one of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol or polyethyleneglycol ethers of octanol, decanol, dodecanol, tetradecanol, hexadecanol, octadecanol, octadec-9-enol.

2. **Number average molecular weight of polymer**

The theoretical average is high but a reasonable minimum is 17,000 Daltons.

3. **Method used to determine the number average molecular weight** (e.g. Gel permeation chromatography) AND a representative chromatogram PR Notice 86-5 format.

It is impossible to analyze the molecular weight of the polyurethane-type polymers (no mobile/soluble polymer molecules are detectable). Alternatively, we estimate the molecular weight from the polymer particle's size (assuming one particle is one molecule). If the particle's diameter were 10 μm, the MW would be 3.8×1014 g/mol. A smaller particle at the typical threshold for nanomaterial's, 0.1 μm would have MW of $3.8x10^8$ g/mol, so we proposed this MW as the lower limit to exclude nanomaterial's.

4. **% oligomer material below molecular weight** 1000 and % oligomer material below molecular weight 500 are less than 0.1%.

5. List of monomers used in the preparation

Compound	CAS number
4,4'-methylene-bis-1,1'-cyclohexanediisocyanate	5124-30-1
2,4,4-trimethyl-1,6-hexanediisocyanate	15646-96-5
5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate)	4098-71-9
1,6-hexanediisocyanate	88357-62-4
polyethylenglycol	25322-68-3
1-octanol	111-87-5
1-nonanol	143-08-8
1-decanol	112-30-1
1-undecanol	112-42-5
1-hexadecanol	36653-82-4
1-octadecanol	112-92-5

6. **Statement of meeting the polymer definition in 40 CFR §723.250(b) and low risk criteria.** The polyurethane-type polymers proposed for tolerance exemption qualify under the low risk polymer definition and description under 40 CFR §723.250 by meeting the chemistry and molecular weight requirements. Polyurethane-type polymers are not cationic and are not designed to depolymerize and the ingredients are on the TSCA inventory. Polyurethane-type polymers are not water absorbing and do not contain perfluoroalkyl moieties and therefore qualify as low risk polymers under the definition.

Aggregate Risk Assessment and Determination of Safety:

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned exemption from the requirement of a tolerance for residues of Polyurethane-type polymers, listed in this petition and description of the chemistry when used as inert ingredients in pesticide formulations applied to growing crops or food-producing animals. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children for the low risk polymer classification.

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Polyurethane-type polymers are not acutely toxic by the oral and dermal routes of exposure, or via inhalation under normal use conditions. Concentrated materials are generally not corrosive, eye and skin irritants and not dermal sensitizers. There is no evidence that Polyurethane-type polymers are neurotoxic, mutagenic, or clastogenic.

Specific information on the studies evaluated and the nature of the adverse effects findings by Polyurethane-type polymers as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in documents allowing the approval of defined low risk polymeric compounds.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD).

The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/pesticides/factsheets/riskassess.htm.

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C. Exposure Assessment

1. **Dietary exposure from food and feed uses.** In evaluating dietary exposure to Polyurethane-type polymers, EPA considered exposure under the polymer exemption classification and established a definition for molecules that meet the criteria of that definition qualify for exemption from the requirement of a tolerance. EPA assessed dietary exposures from large molecular weight polymers in food as follows:

i. First acute and chronic exposure; In conducting the acute and chronic dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for the Polyurethane-type polymers. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the dietary exposure and risk assessment for low risk polymers can be found at http://www.regulations.gov.

In the assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

Syngenta believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk based on the EPA assessment and definition requirements for these polymers. Assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 15 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide

product relative to that of the active ingredient. In the case of Cross-linked epoxy-type polymers, EPA made a specific definition of what constitutes an acceptable polymeric compound and the proposed exemption for Polyurethane-type polymers meets that criteria.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the conservative assumptions will lead to a significant exaggeration of actual exposures. Syngenta does not believe that this approach underestimates exposure in the absence of residue data.

ii. Cancer. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential carcinogenicity of several representative large molecular weight polymers such as the Polyurethane-type polymers and no structural alerts for carcinogenicity were identified in any case. Polyurethane-type polymers are not expected to be carcinogenic. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.

iii. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for Polyurethane-type polymers. Tolerance level residues and/or 100 percent CT were assumed for all food commodities.

2. **Dietary exposure from drinking water**. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for Polyurethane-type polymers in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of large molecular weight polymers. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at: http://www.epa.gov/oppefed1/models/water/index.htm.

Human Health Risk Assessment to support the proposed exemption from the requirement of a tolerance for Polyurethane-type polymers, when used as inert ingredients in pesticide formulations meets the requirements of the EPA definition of an exempt polymer.

3. **Non-dietary exposure.** The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Polyurethane-type polymers may be used as inert ingredients in pesticide products that are registered for specific uses that could result in indoor residential exposures.

A screening level residential exposure and risk assessment was completed for polymeric products used as inert ingredients in pesticide formulations. In this assessment,

representative scenarios, based on end-use product application methods and labeled application rates, were selected. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for outdoor scenarios with high exposure potential (i.e., exposure scenarios with high end unit exposure values) to

serve as a screening assessment for all potential residential pesticides containing Polyurethane-type polymers. Similarly, residential post application dermal and oral exposure assessments were also performed utilizing high end outdoor exposure scenarios. Analysis can be found at http://www.regulations.gov in documents on the polymer exemption risk assessment.

4. **Cumulative effects from substances with a common mechanism of toxicity.** Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity.

Syngenta has not found that Polyurethane-type polymers share a common mechanism of toxicity with any other substances, and Polyurethane-type polymers do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, Syngenta has assumed that Polyurethane-type polymers do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Conclusion. Syngenta has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for low risk polymers including Cross-linked epoxy-type polymers is considered adequate for assessing the risks to infants and children.

ii. There is no indication that Cross-linked epoxy-type polymers are neurotoxic chemicals and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence Polyurethane-type polymers result in increased susceptibility in in utero rats in prenatal developmental studies.

iv. No chronic studies on Polyurethane-type polymers are available; however, there is no need to add additional UFs to account for an incomplete toxicity database because the surrogate data support the lack of chronic effects.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 percent crop treated is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to polymers that meet the low risk criteria in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by Polyurethane-type polymers.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

In conducting this aggregate risk assessment, the Agency has determined that polymers that meet the definition of low risk polymers, do not pose an unreasonable risk to man and the environment.

1. Acute risk. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure.

2. Chronic risk. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water using the exposure assumptions discussed in this unit for chronic exposure.

3. Short-term risk. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

5. Determination of safety. Based on these risk assessments, Syngenta concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of Polyurethane-type polymers.

Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

Syngenta is not aware of any country requiring a tolerance for Polyurethane-type polymers nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

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USE RECOMMENDATIONS

A. Pesticides Tolerance exemptions are requested for Polyurethane-type polymers when used as inert ingredient in pesticide formulations as illustrated in Table 1. This list of Polyurethane-type monomers is not intended to be an inclusive list of all the possible combinations of acceptable Polyurethane-type monomers. Table 2 lists the proposed monomers that can be used to create the high molecular weight polymers for which tolerance exemptions are requested.

Table 1: Tolerance Exemptions Being Requested in this Petition.

40 CFR 180	Tolerance Exemption Expression	Uses	CAS Registry Number Name
960*	Polyurethane-type polymers	All	1161844-26-3 Polyurethane-type polymers
960*	Polyurethane-type polymers	All	1161844-30-9 Polyurethane-type polymers
960*	Polyurethane-type polymers	All	1161844-43-4 Polyurethane-type polymers
960*	Polyurethane-type polymers	All	1161844-51-4 Polyurethane-type polymers
960*	Polyurethane-type polymers	All	1161844-53-6 Polyurethane-type polymers
960*	Polyurethane-type polymers	All	693252-31-2 Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-hydroxy-, polymer with 1,6-diisocyanato-2,2,4-trimethylhexane and 1,6-diisocyanato-2,4,4-trimethylhexane, C10-rich C9-11-branched and linear alc.-blocked
960*	Polyurethane-type polymers	All	162993-60-4 Oxirane, polymer with 1,6-diisocyanatohexane, stearyl alc.-blocked
960*	Polyurethane-type polymers	All	630102-86-2 Poly(oxy-1,2-ethanediyl), alpha.,.alpha.',.alpha."-1,2,3-propanetriyltris[.omega.-hydroxy-, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 1-decanol- and 1-octanol-blocked

*Substances listed in 40 CFR 180.960 inert ingredients exempt from the requirement of a tolerance used in pesticide formulations.

Table 2: Polyurethane Monomers

List of monomers used in the preparation

Compound	CAS number
4,4'-methylene-bis-1,1'-cyclohexanediisocyanate	5124-30-1
2,4,4-trimethyl-1,6-hexanediisocyanate	15646-96-5
5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (isophoronediisocyanate)	4098-71-9
1,6-hexanediisocyanate	88357-62-4